

REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The objection to claim 46 under 37 C.F.R. § 1.75(c) for being of improper dependent form is obviated in view of the cancellation of the claim.

The rejection to claims 1, 3-9, 18-23, 31, 33, 35-38, 43, 44, and 46 under 35 U.S.C. § 112 (2nd para.) for indefiniteness is respectfully traversed in view of the above amendments to the "if present in the sample" limitation in claims 1, 31, 35, and 37 and the following remarks.

It is the position of the U.S. Patent and Trademark Office ("PTO") that claim 1 (as well as claims 3-9, 18-23, 38, 43, and 44, which are dependent on claim 1) and claim 31 (as well as claims 33 and 46, which are dependent on claim 31) are indefinite because the phrase "when deposited" as recited in the claims renders the claims confusing as to whether the reagent is a definite part of the system or not.

Applicants submit that, for the reasons noted below, the claims sufficiently define the scope of the phrase such that one of ordinary skill in the art would fully understand its meaning.

The rejected phrase is recited in claims 1 and 31, which are directed to a system and a kit, respectively, for assaying one or more targets in a sample comprising: (a) an assay device having one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety immobilized to one or more of the at least two electrodes, the recognition moiety being capable of specific binding to a component of one of the targets; (b) an electric or electronic module; and (c) reagents formulated to deposit a conductive substance onto a complex formed between the recognition moiety and the target, where the conductive substance, when deposited onto the complex, forms a conductive bridge between the at least two of the electrodes of a set. One of ordinary skill in the art, reading these claims, would fully understand that the reagent formulated to deposit a conductive substance onto a complex formed between the recognition moiety and the target is a definite part of the system/kit and would not regard the phrase "when deposited" as indefinite.

This is apparent from the literal language of claims 1 and 31, which recites a system/kit for assaying one or more targets in a sample comprising "reagents formulated to

deposit a conductive substance onto a complex between said recognition moiety and said target, wherein the reagents comprise: (i) a solution comprising nucleation-center forming entities for binding to said target if said target is present in the sample; and (ii) a combination of metal ions and a reducing agent to allow formation of said conductive substance on said entities, and wherein the conductive substance, when deposited onto the complex, forms a conductive bridge between the at least two of the electrodes of a set." Thus, it is clear from the language of the claims that the reagents formulated to deposit a conductive substance onto a complex between the recognition moiety and the target are part of the claimed assay system/kit, as also acknowledged by the examiner on page 4, lines 4-5 of the outstanding office action. While the reagents are a part of the claimed assay system/kit, a reading of the claims clearly indicates that a complex is first formed between the recognition moiety and a target only if the target is present in the sample, and it is only when that complex is formed that the conductive substance, formed by the combination of metal ions and a reducing agent included in the reagents, is deposited onto the complex forming a conductive bridge between the electrodes. Thus, one of ordinary skill in the art would fully comprehend the meaning of the phrase "when deposited."

For example, the present application, at page 8, lines 3-5 and 17-20 and page 9, lines 1-4, describes when a conductive bridge forms between the at least two electrodes of the assay set. Thus, formation of the conductive bridge occurs in the presence of reagents for growing a conductive substance between the electrodes, only if a complex between the target and the recognition moiety is formed (page 8, lines 3-5). In addition, according to one aspect of the invention, the conductive bridge is formed by growing conductive substance on nucleation-center forming entities which are either bound to or deposited on the complex formed between the recognition moiety and the target (page 8, lines 17-20). The conductive substance forms a conductive bridge between at least two of the electrodes of the assay set (page 9, lines 1-4).

Since the meaning of the claims is readily apparent to one of ordinary skill in the art, the rejection under 35 U.S.C. §112 (2nd para.) should be withdrawn.

The rejection to claims 10, 12, 13, 15, 16, and 34 under 35 U.S.C. § 112 (1st para.) for lack of written descriptive support is respectfully traversed in view of the above amendments to the claims.

The rejection to claims 30, 40, and 42 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed in view of the above amendments to the claims.

The rejection of claims 1, 3-5, 10-13, 15, 16, 24-29, 35, 36, 39, 41, and 43-45 under 35 U.S.C. § 102(b) as anticipated by Braun et al., "DNA-Templated Assembly and Electrode Attachment of a Conducting Silver Wire," *Nature*, 391:775-778 (1998) ("Braun") is respectfully traversed in view of the above amendments and the following remarks.

Braun discloses a two-step procedure allowing the application of DNA to the construction of functional circuits, where hybridization of a DNA molecule with surface-bound oligonucleotides is first used to stretch the DNA molecule between two gold electrodes, and the DNA molecule is then used to grow a conductive silver wire.

However, Braun does not in any way teach or suggest a system or a device having assay sets, each of the assay sets including at least two electrodes and a recognition moiety immobilized to one or more of the at least two electrodes, the recognition moiety being capable of binding to a component of a target selected from the group consisting of a bacterium, a virus, and a cell, as set forth in amended claims 1, 3-5, 35, 36, 41, and 43-44 of the present application. (Support for the amendments to the claims is found on page 1, lines 6-8 of the present application.) Braun also fails to teach or suggest a method for assaying or detecting one or more biological molecule targets in a sample, as set forth in claims 24-29, 39, and 45 of the present application. More specifically, Braun does not teach or suggest a system for assaying one or more targets in a sample comprising an assay device having one or more assay sets at least one for each target to be assayed, each of the assay sets comprising at least two electrodes and a recognition moiety immobilized to one or more of the at least two electrodes, "the recognition moiety being capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell" as required by amended claim 1 (as well as dependent claims 3-5, 43, and 44) of the present application. Nor does Braun teach or suggest an electronic device for determining one or more targets in a sample, comprising an integrated circuit comprising a first group of N_1 conductors and a second group of N_2 conductors, defining between them $N_1 \times N_2$ junctions, each such junction being formed with an electronic module comprising two electrodes, each pair of electrodes forming part of an assay set, each assay set having "a recognition moiety for binding to a component of a target selected from the group consisting of a bacterium, a virus, and a cell" as required by amended claim 35 (as well as dependent claims 36 and 41) of

the present application. Braun also does not in any way teach or suggest "methods for assaying one or more biological molecule targets in a sample" by providing an assay device having at least two electrodes, contacting the assay device with a sample, contacting the assay device with a reagent to form a conductive bridge between the electrodes, connecting the electrodes to an electric or electronic module, and determining the conductance between the two electrodes, where conductance above a threshold conductance indicates the presence of a respective target in the sample, as required by claims 24-26 (as well as dependent claims 27-29, 39, and 45) of the present application. Since Braun does not teach or suggest the claimed system and electronic device that have recognition moieties capable of binding to a component of a target such as bacterium, a virus, and a cell, or the claimed methods that assay or detect one or more biological molecule targets in a sample, the rejection based on this reference is improper and should be withdrawn.

The rejection of claims 31, 33, 34, and 46 under 35 U.S.C. § 103(a) for obviousness over Braun is respectfully traversed in view of the above amendments and the following remarks.

It is the PTO's position that it would have been obvious to one of ordinary skill in the art to package the device and the reagents employed by Braun into the claimed kit in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, etc.

Applicants disagree. Braun does not in any way teach or suggest a kit for use in assaying one or more targets in a sample comprising an assay device having a recognition moiety capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell, as set forth in amended claims 31 and 33 of the present application. More specifically, Braun does not teach or suggest a kit for use in assaying one or more targets in a sample, comprising an assay device having one or more assay sets, each of the assay sets including at least two electrodes and a recognition moiety immobilized to one or more of the at least two electrodes, "the recognition moiety being capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell" as required by amended claim 31 (as well as dependent claim 33) of the present application. Since Braun does not teach or suggest the claimed kit that has recognition moieties capable of binding to targets such as bacterium, a

virus, and a cell, the obviousness rejection based on this reference is improper and should be withdrawn.

The rejection of claims 6-9, 18-21, 37, and 38 under 35 U.S.C. § 103(a) for obviousness over Braun is respectfully traversed in view of the above amendments and the following remarks.

It is the PTO's position that it would have been obvious to one of ordinary skill in the art to duplicate the assay set of Braun to arrive at the present invention of a system comprising multiple assay sets, as claimed in claims 18-21, and 38, or device, as claimed in claim 37. In addition, it is the PTO's position that it would have obvious to one of ordinary skill in the art to use metal particles other than silver which conduct electricity such as platinum or gold for the purpose of metallizing the bridge formed between the electrodes of Braun, as claimed in claims 6-9.

As already noted above, Braun fails to teach or suggest the present invention of amended claim 1, from which claims 6-9, 18-21, and 38 depend. In particular, Braun does not teach or suggest a system for assaying one or more targets in a sample comprising an assay device having one or more assay sets at least one for each target to be assayed, each of the assay sets comprising at least two electrodes and a recognition moiety immobilized to one or more of the at least two electrodes, the recognition moiety being capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell, as required by amended claim 1 of the present application.

Thus, Braun could not have rendered obvious the subject matter of claims 6-9, 18-21, and 38.

In addition, Braun fails to teach or suggest an electric device for determining one or more targets in a sample comprising electrodes forming part of an assay set, each assay set having a recognition moiety for binding to a component of a target selected from the group consisting of a bacterium, a virus, and a cell, as required by amended claim 37.

Since Braun does not teach or suggest the claimed system and electric device that have recognition moieties capable of binding to targets such as bacterium, a virus, and a cell, the obviousness rejection based on this reference is improper and should be withdrawn.

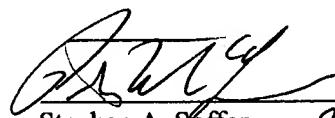
The provisional rejection of claims 1, 3-13, 15, 16, 18-23, 31, 33-38, 43, 44, and 46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 and 19-32 of copending U.S. Patent Application Serial No.

09/462,171 (now issued as U.S. Patent No. 6,946,675 on September 20, 2005) is respectfully traversed in view of the attached terminal disclaimer.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: 11 January 2006


Stephen A. Soffen *Patent Attorney*
Registration No. 31,063 *35,947*

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L Street NW
Washington, DC 20037-1526
Telephone: (202) 828-4879
Facsimile: (202) 887-0689